Veterinary Medicines Directorate

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Post Authorisation Assessments

Ubropen 600 mg Intramammary Suspension for Lactating Cows

Vm 42810/4000

•	08 May 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	13 June 2023	Addition of a secondary packaging site of a finished product. (NI)
•	22 December 2022	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: Change to in-process tests or limits applied during the manufacture of the finished product:
•	22 December 2022	Variation to update the ASMF.
•	11 October 2022	Addition of a new in-process test and limits applied during the manufacture of the finished product.
•	16 June 2022	Addition of a secondary packaging site of a finished product.
•	19 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 April 2021	Renewal – UK as CMS.
•	06 July 2020	Repeat Use MRP to add 4 new member states
•	01 February 2019	Change in distributor details. From Vetcare Oy, P.O. Box 99, 24101 Salo, Finland to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	23 October 2018	Addition of a supplier of packaging components or devices. Replacement of a specification parameter of the finished product.
•	14 September 2018	Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Addition of a test procedure for the finished product. Addition of test method on the finished product specifications. Addition of a manufacturing site for part of the manufacturing process of the finished product. Addition of a manufacturing site of the finished product.
•	09 May 2018	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	27 September 2017	Addition of a site where batch control/testing takes place. Change in the sterilising method of the final product.

•	19 July 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Changes to the DDPS.
•	26 May 2017	Increase in the shelf-life of the finished product as packaged for sale, from 1 year to 2 years.
•	24 May 2017	Change in the invented name of the veterinary medicinal product from Caremast Vet 600 mg Intramammary Suspension for Lactating Cows to Ubropen 600 mg Intramammary Suspension for Lactating Cows.